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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,884	02/26/2002	Gregory N. Beatch	480102.409USPC	6014

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EXAMINER	
ANDERSON, REBECCA L	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,884	BEATCH ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,38-47,72-75 and 84-114* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,40,42,44,46,72,74,84 and 105* is/are rejected.

7)☒ Claim(s) *1-3,38,40,42,44,46,72,74,84,90-92,105,108 and 114* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-7,39,41,43,45,47,73,75,85-89,93-104,106,107 and 109-113.

DETAILED ACTION

Claims 1-3, 5-7, 38-47, 72-75 and 84-114 are currently pending in the instant application. Claims 5-7, 39, 41, 43, 45, 47, 73, 75, 85-89, 93-104, 106, 107 and 109-113 are withdrawn from consideration as being for non-elected subject matter. Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 are objected and claims 38, 40, 42, 44, 46, 72, 74, 84 and 105 are rejected.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 21 October 2004 is acknowledged. The traversal is on the ground(s) that the examiner has failed to satisfy the requirements for lack of unity for Groups I-V directed to compounds and fails to satisfy the requirements for lack of unity for Group VI-XXXIII directed to methods and has improperly applied the lack of unity criteria to compound claims having Markush groups and improperly interprets the rules relating to unity of invention with respect to method groups. This is not found persuasive because while applicant is arguing that the examiner has improperly applied the lack of unity criteria to Markush claims, the applicant has discussed the same structural element that is in common in all the claims as noted by the examiner on page 14 of the lack of unity requirement. It is noted that the claims lack unity under PCT rule 13.1 and 13.2, since this structural element in common with the claims is not a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. Since the claims do not contain a special technical feature that defines a contribution over the prior art, as can be seen by the structural element in common in all the claims being found in US Patent

NO. 5,506, 257, unity of invention is correctly considered to be lacking and restriction of the invention is considered to be proper. Applicant has further argued that the PCT examiner did not reject claim 1 for lack of unity of invention, however, it is noted that according to 37 CFR 1.499, if the examiner finds that a national stage application lacks unity of invention under 1.475, the examiner may in an office action require applicants in the response to that action to elect the invention to which the claims shall be restricted. It is noted that the only corresponding technical feature is the feature as found on page 14 of the restriction requirement and therefore, this technical feature does not define a contribution of the claimed invention over the prior art. Applicant argues that 37 CFR 1.475(b) does not apply to the pending claims, however, it is noted that 37 CFR 1.475(c) states that if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present. Applicants' instant claims contain more than one of the combinations of categories of invention set forth in paragraph (b) and that is why 37 CFR 1.475(b) is stated to support the lack of unity requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 are objected to as containing non-elected subject matter. Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 are presented drawn solely to the elected invention of Group II and free of the following 35 USC 112 1st paragraph rejection would appear allowable over the prior art of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 40, 42, 44, 46, 72, 74, 84 and 105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is pharmaceutical compositions for the treatment of disorders such as cardiovascular disease, cerebral or myocardial ischemias, hypertension, long-QT syndrome, stroke, to produce analgesia or anesthesia, heart failure, enhance libido, central nervous system diseases, convulsions, epileptic spasms, depression, anxiety, schizophrenia, Parkinson's disease, respiratory disorders, cystic

fibrosis, asthma, cough, inflammation, arthritis, allergies, gastrointestinal disorders, incontinence, irritable bowel syndrome, migraine, ophthalmic diseases, diabetes mellitus, myopathies, Becker's myotonia, myasthenia gravis, paramyotonia congentia, malignant hyperthermia, hyperkalemic periodic paralysis Thomsen's myotonia, autoimmune disorders, graft rejection in organ transplantation or bone morrow transplantation, hypotension, Alzheimer's disease, dementia, or alopecia by blocking an ion channel.

The state of the prior art and the predictablility or lack thereof in the art

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of disorders, whether or not the disease is effected by blocking ion channels would make a difference.

It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer's disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease. (URL:http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html).

Hence, in the absence of a showing of correlation between all the disorders claimed as capable of treatment by blocking ion channels one of skill in the art is unable to fully predict possible results from the administration of the compositions due to the unpredictability of the role of the ion channels, and since the treatment of Alzheimer's disease is mediated by the breakdown of acetylcholine or the inhibition of excess amounts of glutamate.

The amount of direction or guidance present and the presence or absence of working examples

The only direction and guidance present in the specification is a list of disorders that applicant considers and the data on pages 38-51 for the treatment of arrhythmia in warm blooded animals. There is no correlation between blocking ion channels with any disorder besides arrhythmia, let alone Alzheimer's disease, and the specification does not provide any pharmaceutical data for the treatment of any specific disorder, i.e. the specification is silent and fails to provide guidance as to what diseases are mediated by

blocking ion channels, except for the treatment of arrhythmia. There no other guidance or direction present as to what autoimmune diseases, cardiovascular diseases, central nervous system diseases, etc. can be treated and there is no guidance as to how these other diseases can be treated.

The breadth of the claims

The breadth of the claims is pharmaceutical compositions for the treatment of disorders such as cardiovascular disease, cerebral or myocardial ischemias, hypertension, long-QT syndrome, stroke, to produce analgesia or anesthesia, heart failure, enhance libido, central nervous system diseases, convulsions, epileptic spasms, depression, anxiety, schizophrenia, Parkinson's disease, respiratory disorders, cystic fibrosis, asthma, cough, inflammation, arthritis, allergies, gastrointestinal disorders, incontinence, irritable bowel syndrome, migraine, ophthalmic diseases, diabetes mellitus, myopathies, Becker's myotonia, myasthenia gravis, paramyotonia congentia, malignant hyperthermia, hyperkalemic periodic paralysis Thomsen's myotonia, autoimmune disorders, graft rejection in organ transplantation or bone morrow transplantation, hypotension, Alzheimer's disease, dementia, or alopecia by blocking an ion channel.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what disorders out of all disorders would be benefited by the blocking of ion channels and would furthermore then have to determine which of the claimed compounds would provide treatment of the disorder.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the composition for the treatment of disorders such as cardiovascular disease, cerebral or myocardial ischemias, hypertension, long-QT syndrome, stroke, to produce analgesia or anesthesia, heart failure, enhance libido, central nervous system diseases, convulsions, epileptic spasms, depression, anxiety, schizophrenia, Parkinson's disease, respiratory disorders, cystic fibrosis, asthma, cough, inflammation, arthritis, allergies, gastrointestinal disorders, incontinence, irritable bowel syndrome, migraine, ophthalmic diseases, diabetes mellitus, myopathies, Becker's myotonia, myasthenia gravis, paramyotonia congentia, malignant hyperthermia, hyperkalemic periodic paralysis Thomsen's myotonia, autoimmune disorders, graft rejection in organ transplantation or bone morrow transplantation, hypotension, Alzheimer's disease, dementia, or alopecia by blocking an ion channel. As a result necessitating one of skill to perform an exhaustive search for which disorders can be treated by what compositions in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its

successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which disorders can be treated by the compound encompassed in the instant claims, with no assurance of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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